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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/092,546	06/05/1998	BEAT KINDLER	6348	6213

25763 7590 07/02/2003

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EXAMINER

DESANTO, MATTHEW F

ART UNIT PAPER NUMBER

3763

DATE MAILED: 07/02/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/092,546

Applicant(s)

KINDLER ET AL.

Examiner

Matthew F DeSanto

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 April 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 6-36 is/are pending in the application.
- 4a) Of the above claim(s) 10-14, 19, 22-25 and 27-36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,6-9, 15-18, 20, 21 and 26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

1. Newly submitted claim 27-36 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claims 27-35 are drawn to the valve and thus is restricted by combination-subcombination, and claim 36 is drawn to the method of administering fluid and thus is restricted by process and apparatus.

2. Inventions I [claims 1-26] and II [claims 27-35] are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the subcombination does not have an inlet and an outlet as well as being used with a catheter and piston. The subcombination has separate utility such as being used as a filter.

3. Inventions III [claim 36] and I [claims 1-27] are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the process is claimed with any check valve that has a threshold pressure for opening the valve, not necessarily an apparatus with a piston and separate housing.

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Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 27-36 withdrawn from consideration as being directed to a non-elected invention as well as claims 10-14, 19, 23-25. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1, 2, 6-9, 15-18, 20-21, and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Lee (USPN 3759425).

Lee discloses a device for metered administering fluid of a fluid comprising a container having a piston through an outlet, a catheter connected to the outlet to the container having a front end and will inherently contain an injection needle. He teaches a valve having an inlet and an outlet and injection needle that can be attached to the distal end, the valve having an inlet and outlet end wherein flow of fluid is permitted from the outlet to the injection needle when pressure is exerted on the inlet end of the valve

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exceeds a pressure on the inlet end caused by the pressure of the fluid drug. (Figures 1-8, and entire reference)

6. Claims 1, 2, 6-9, 15 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Abramson (USPN 4,143,853).

Abramson discloses a device for metered administering fluid of a fluid comprising a container having a piston through an outlet, a catheter connected to the outlet to the container having a front end and will inherently contain an injection needle. He teaches a valve having an inlet and an outlet and injection needle that can be attached to the distal end, the valve having an inlet and outlet end wherein flow of fluid is permitted from the outlet to the injection needle when pressure is exerted on the inlet end of the valve exceeds a pressure on the inlet end caused by the pressure of the fluid drug. (Figures 1-6, and entire reference)

7. Claims 1, 2, 6-9, 15 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Cardenas (USPN 5616133).

Cardenas discloses a device for metered administering fluid of a fluid comprising a container having a piston through an outlet, a catheter connected to the outlet to the container having a front end and will inherently contain an injection needle. He teaches a valve having an inlet and an outlet and injection needle that can be attached to the distal end, the valve having an inlet and outlet end wherein flow of fluid is permitted from the outlet to the injection needle when pressure is exerted on the inlet end of the valve exceeds a pressure on the inlet end caused by the pressure of the fluid drug. (Figures 1-4, 12, and entire reference)

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Response to Arguments

8. Applicant's arguments filed 4/17/03 have been fully considered but they are not persuasive.
9. With regards to Lee not disclosing an ampoule this is taught with reference number 24 in Figure 5 in Lee.
10. With regards to Lee not disclosing the use of a catheter extending from the outlet of container; this is taught with reference number 12 and 40, wherein the reference number teach a needle mount, which inherently teaches mounting a needle or catheter, which is well known in the art, as shown in Michel et al. (USPN 4,969,874) or Alchas (USPN 4,772,273) as well as being supported in the Lee reference.
11. With regards to Lee not disclosing a valve that remains closed until the upstream surface of the valve is subject to an opening pressure, this is taught in Lee column 7, lines 51-62 as well as the entire reference.

Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew F DeSanto whose telephone number is 1-703-305-3292. The examiner can normally be reached on Monday-Friday 8:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 1-703-308-3552. The fax phone numbers for the organization where this application or proceeding is assigned are 1-703-872-9302 for regular communications and 1-703-872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 1-703-308-0858.



Matthew DeSanto
Art Unit 3763
June 25, 2003



BRIAN L. CASLER
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700